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10/500,672	07/02/2004	Maria A. Bednarek	20954P	3103

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1656

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/500,672

Applicant(s)

BEDNAREK, MARIA A.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 August 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21, 23 and 25-28 is/are pending in the application.
- 4a) Of the above claim(s) 21, 23 and 25-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7/2/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION*****Election/Restrictions***

1. In the response to the restriction requirement filed August 1, 2006, Applicants elect Group I, claims 1-20 and SEQ ID NO: 29 with traverse. Claim 18 has been amended to the elected sequence. The traversal is on the ground(s) that a special common technical feature present in the different groups is the same generic peptide which can encompass patently distinct species, the restriction does not address the common technical feature of the optionally substituted peptide referred to in the different claims, but rather notes additional features may be present, and the presence of additional features does not take away from the above noted special common technical feature (pages 8-9 of the response). The response has been considered, however, the argument is not found fully persuasive, because each group is directed to distinct peptides and/or methods, where the peptides of generic formula contain different amino acid sequences and produce different effects, and the methods in each group have different method steps and outcomes. Accordingly, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept and lack of unity is deemed proper. Regarding the specific peptide sequences, SEQ ID NOs:29-34, although they are patentably distinct from each other, upon reconsideration, SEQ ID NO:30-34 along with SEQ ID NO:29 will be included for examination. Therefore, Claims 1-20 and SEQ ID NO:29-34 are examined.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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2. Claims 1-18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim is drawn to an optionally substituted peptide. As written, the claim does not explicitly indicate the hand of man. Insertion of "isolated", "synthetic" or "purified" in connection with the optionally substituted peptide is suggested. See MPEP § 2105.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-16 and 19-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific peptides in the structure of formula,  $Z^1-X^1-X^2-X^3-X^4-X^5-X^6\text{-cyclo}(X^7-X^8-X^9-X^{10}-X^{11}-X^{12}-X^{13}-X^{14}-X^{15}-X^{16})-X^{17}-Z^2$  such as the amino acid sequences listed in Tables 1-4, and a method of screening for a compound able to bind MCH-1R using these peptides; and certain MCH analogs as indicated in the prior art, does not reasonably provide enablement for all peptides (at least  $9 \times 10^{16}$  sequences without including the peptides having amino acids derivatives or higher homologs or labels) in an optionally substituted peptide having the structure of formula  $Z^1-X^1-X^2-X^3-X^4-X^5\text{-cyclo}(X^6-X^7-X^8-X^9-X^{10}-X^{11}-X^{12}-X^{13}-X^{14}-X^{15}-X^{16})-X^{17}-Z^2$  or  $Z^1-X^1-X^2-X^3-X^4-X^5-X^6\text{-cyclo}(X^7-X^8-X^9-X^{10}-X^{11}-X^{12}-X^{13}-X^{14}-X^{15})-X^{16}-X^{17}-Z^2$ , or a labeled derivative of the peptide; and a method of screening for a compound able to bind a MCH type 1 receptor (MCH-1R) by measuring the ability of the compound to affect binding of the peptide to the receptor. The specification does not enable any person skilled in the art to

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which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 1-16 and 19-20 are directed to an optionally substituted peptide having the structure of  $Z^1-X^1-X^2-X^3-X^4-X^5-X^6\text{-cyclo}(X^7-X^8-X^9-X^{10}-X^{11}-X^{12}-X^{13}-X^{14}-X^{15}-X^{16})-X^{17}-Z^2$  or  $Z^1-X^1-X^2-X^3-X^4-X^5-X^6\text{-cyclo}(X^7-X^8-X^9-X^{10}-X^{11}-X^{12}-X^{13}-X^{14}-X^{15})-X^{16}-X^{17}-Z^2$ , or a labeled derivative of the peptide (claims 1-16) and a method of screening for a compound able to bind MCH-1R using the peptide (claims 19-20). The specification, however, only discloses cursory conclusions (pages 2-5) without data supporting the findings, which state that the present invention provides truncated hMCH analogs selectively active at MCH-1R over MCH-2R, which contain an  $X^6$  being a D-amino acid, 5-guanidinopropionic acid or its lower or higher homologs, or a derivative thereof; and a  $X^{10}$  which is either asparagine, glutamine, alanine, leucine, isoleucine, valine, norleucine, cyclohexylalanine, phenylalanine, (2')-naphthylalanine, tyrosine, histidine, tryptophan, lysine, serine, threonine, methionine, or a derivative thereof in an optionally substituted peptide having the structure of  $Z^1-X^1-X^2-X^3-X^4-X^5-X^6\text{-cyclo}(X^7-X^8-X^9-X^{10}-X^{11}-X^{12}-X^{13}-X^{14}-X^{15}-X^{16})-X^{17}-Z^2$  or  $Z^1-X^1-X^2-X^3-X^4-X^5-X^6\text{-cyclo}(X^7-X^8-X^9-X^{10}-X^{11}-X^{12}-X^{13}-X^{14}-X^{15})-X^{16}-X^{17}-Z^2$ , and a method of screening for a compound that binds a MCH-1R using the truncated MCH analogs. There are no indicia that the present application enables the full scope in view of the truncated MCH analogs and a method of screening for a compound that binds MCH-1R using the truncated MCH analogs as discussed in the stated rejection. The present application does not provide sufficient teaching/guidance for enabling the full scope of the claims. The factors considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d at 731,737, 8 USPQ2d at 1400,1404 (Fed. Cir.1988)). The factors most

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relevant to this rejection are the breadth of the claims, the presence or absence of working examples, the state of the prior art and relative skill of those in the art, the predictability or unpredictability of the art, the nature of the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

(1). The breadth of the claims:

The breadth of the claims is broad and encompasses unspecified variants regarding the amino acid sequences of the claimed peptides or their labeled derivatives, and the derivatives or higher homologs of the amino acid residues in the peptides, which are not adequately described or demonstrated in the specification.

(2). The presence or absence of working examples:

The specification indicates synthesis of certain MCH analogs, measurement of MCH receptor activity assay, and measurement of activities of truncated MCH analogs using competition binding assay and MCH receptor activity assay (Examples 1-7; Tables 1-4). However, there are no working examples indicating the make/use of peptides having various amino acid derivatives, higher homologs or labels.

(3). The state of the prior art and relative skill of those in the art:

The prior art (e.g., Maratos-Flier *et al.*, U. S. Patent 5,849,708) teaches certain MCH analogs. However, the general knowledge and level of the skill in the art do not supplement the omitted description, the specification needs to provide specific teachings on the identities of MCH peptides that contain various amino acid derivatives, higher homologs or labels and are selectively active at MCH-1R over MCH-2R to be considered enabling for variants.

(4). Predictability or unpredictability of the art:

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The claims encompass numerous truncated MCH analogs and a screening method for identifying a compound that binds to MCH-1R using the truncated MCH analogs, however, the identities of MCH analogs containing various amino acid derivatives, higher homologs or labels are not sufficiently described in the specification, thus the invention is highly unpredictable regarding the sequences of active MCH analogs that are selective at MCH-1R over MCH-2R.

(5). The amount of direction or guidance presented and the quantity of experimentation necessary:

The claims are directed to various truncated MCH analogs and a screening method for identifying a compound that binds to MCH-1R using the truncated MCH analog. The specification indicates synthesis of certain MCH analogs, measurement of MCH receptor activity assay, and measurement of activities of truncated MCH analogs using competition binding assay and MCH receptor activity assay (Examples 1-7; Tables 1-4). While the specification further assert that “a derivative thereof” refers to the corresponding D-amino acid, N-alkyl-amino acid and  $\beta$ -amino acid (page 5, lines 12-14); a labeled derivative indicates the presence of a detectable label, and detectable labels include luminescent, enzymatic and radioactive labels, and a preferred radiolabel is  $^{125}\text{I}$ , and both the type of label and the position of the label can effect MCH activity (page 12, line 32 to page 13, line 2), the specification does not identify any peptide containing an amino acid derivative or higher homolog, or a detectable label. Furthermore, there is no disclosure indicating the make/use of these peptides, and their activity at MCH-1R. Since the specification has not provided sufficient teachings on the make/use of truncated MCH analogs containing amino acid derivative or higher homolog, or a detectable label, it is necessary

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to carry out undue experimentation to identify the MCH peptides that are selectively active at MCH-1R.

(6). Nature of the Invention

The scope of the claims includes numerous variants of truncated MCH analogs, however, the specification has not demonstrated the make/use of MCH peptides containing various amino acid derivatives or higher homologs, or a detectable labels that are active MCH-1R. Thus, the disclosure is not enabling for reasons discussed above.

In summary, the scope of the claim is broad, while the working example does not demonstrate the claimed variants, the sequence of the active MCH analog is unpredictable and the teachings in the specification are limited, therefore, it is necessary to have additional guidance and to carry out undue experimentation to identify the MCH peptides that are selectively active at MCH-1R.

4. Claims 1-16 and 19-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-16 and 19-20 are directed to an optionally substituted peptide having the structure of formula  $Z^1-X^1-X^2-X^3-X^4-X^5\text{-cyclo}(X^6-X^7-X^8-X^9-X^{10}-X^{11}-X^{12}-X^{13}-X^{14}-X^{15}-X^{16})-X^{17}-Z^2$  or  $Z^1-X^1-X^2-X^3-X^4-X^5-X^6\text{-cyclo}(X^7-X^8-X^9-X^{10}-X^{11}-X^{12}-X^{13}-X^{14}-X^{15})-X^{16}-X^{17}-Z^2$ , or a labeled derivative of the peptide, where  $X^1, X^2, X^3, X^4, X^5, X^6, X^7, X^8, X^9, X^{10}, X^{11}, X^{12}, X^{13}, X^{14}, X^{15}, X^{16}$  and  $X^{17}$  can be certain amino acid or a derivative thereof, or a higher homolog of certain amino acid (e.g., 5-guanidinopropionic acid at  $X^6$ ); and a method of screening for a compound



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able to bind a MCH type 1 receptor (MCH-1R) by measuring the ability of the compound to affect binding of the peptide to the receptor. While the specification indicates “a derivative thereof” refers to the corresponding D-amino acid, N-alkyl-amino acid,  $\beta$ -amino acid and  $\omega$ -amino acid (page 5, lines 12-14); a labeled derivative indicates the presence of a detectable label, and detectable labels include luminescent, enzymatic and radioactive labels, and a preferred radiolabel is  $^{125}\text{I}$ , and both the type of label and the position of the label can effect MCH activity (page 12, line 32 to page 13, line 2), the specification does not identify any peptide containing an amino acid derivative or higher homolog, or a detectable label. Furthermore, there is no disclosure indicating the make/use of these peptides, and their activity at MCH-1R. Without guidance on structure to function/activity of these peptide derivatives, one skilled in the art would not know which peptides are functional. The lack of description on the structure to function/activity relationship and the lack of representative species for the peptide derivatives as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-16 and 19-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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6. Claims 1-16 and 19-20 are indefinite because of the use of the term “a derivative thereof”, “a labeled derivative” or “higher homolog”. The term cited renders the claim indefinite, it is unclear what compound the derivative or labeled derivative refers to, and how different the derivative is from the parent amino acid; and what is the metes and bounds for “higher homolog”, e.g., if the parent compound is 5-guanidinopropionic acid (having 3 carbons in the main chain), how many carbons the main chain would have in “higher homolog”. Claims 2-16 and 19-20 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

7. Claims 19-20 are indefinite as to how the compound able to bind MCH-1R is identified, if the claim merely recites the step of measuring the activity of the compound to affect (including inhibiting and enhancing) binding of the peptide to MCH-1R. Claim 20 is included in the rejection because it is dependent on a rejected claim and does not correct the deficiency of the claim from which it depends.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maratos-Flier *et al.* (U. S. Patent 5,849,708).

Maratos-Flier *et al.* disclose MCH agonists having the formula of R<sup>1</sup>-R<sup>2</sup>-R<sup>3</sup>-R<sup>4</sup>-R<sup>5</sup>-R<sup>6</sup>-R<sup>7</sup>-R<sup>8</sup>-R<sup>9</sup>-R<sup>10</sup>-R<sup>11</sup>-R<sup>12</sup>-R<sup>13</sup>-R<sup>14</sup>-R<sup>15</sup>-R<sup>16</sup>-R<sup>17</sup>-R<sup>18</sup>-R<sup>19</sup> (SEQ ID NO:3), among variable substitutions at

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each position, R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, R<sup>4</sup>, R<sup>5</sup> can be deleted; R<sup>6</sup> can be Arg, a conserved amino acid substitution, a D amino acid or deleted; R<sup>7</sup> can be Cys or an amino acid; R<sup>8</sup> can be Met, a conserved amino acid substitution or Cys; R<sup>9</sup> can be Leu, Val or a conserved amino acid substitution; R<sup>10</sup> can be Gly or a conserved amino acid substitution (such as Ala, Table 1); R<sup>11</sup> can be Arg or a conserved amino acid substitution; R<sup>12</sup> can be Val or a conserved amino acid substitution; R<sup>13</sup> can be Tyr or a conserved amino acid substitution; R<sup>14</sup> can be Arg or a conserved amino acid substitution; R<sup>15</sup> can be Pro, a conserved amino acid substitution or Cys; R<sup>16</sup> can be Cys or an amino acid; R<sup>17</sup> can be Trp, a conserved amino acid substitution, an aromatic amino acid or Cys; R<sup>18</sup> can be Gln, Glu or Trp, a conserved amino acid substitution or deleted; R<sup>19</sup> can be Val a conserved amino acid substitution or deleted; if R<sup>7</sup> is Cys, then R<sup>16</sup> is Cys, and the disulfide bond forms between R<sup>7</sup> and R<sup>16</sup>; the preferred embodiments are: R<sup>12</sup> is Val, R<sup>13</sup> is Tyr, R<sup>14</sup> is Arg, R<sup>15</sup> is Pro, R<sup>16</sup> is Cys, R<sup>17</sup> is Trp, the disulfide bond forms between R<sup>7</sup> and R<sup>16</sup>, the agonist is deleted for any or all residues between R<sup>1</sup> and R<sup>6</sup>, and between R<sup>18</sup> and R<sup>19</sup>; one preferred embodiment is MCH(6-17) (column 19, line 43-column 20, line 56; claims 1 and 2). Although the reference does not specifically indicate the amino acid sequence of MCH agonist, it discloses the preferred embodiments for the formula. Thus, at the time of invention was made, it would have been obvious to one of ordinary skill that the MCH agonist can be an amino acid sequence such as D-Arg-cyclo(Cys-Met-Leu-Ala-Arg-Val-Tyr-Arg-Pro-Cys)-Trp (a truncated version of human MCH(6-17)), which results in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

#### ***Claim Rejections-Obviousness Type Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-3, 5-11, 14, 15 and 17-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-30, 34-37 and 42-43 of co-pending Application No. 10/182,509 (based on the claims listed in the preliminary amendment of the co-pending application, filed 2/06/06). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-3, 5-11, 14, 15 and 17-20 in the instant application disclose an optionally substituted peptide having the structure of  $Z^1-X^1-X^2-X^3-X^4-X^5-X^6\text{-cyclo}(X^7-X^8-X^9-X^{10}-X^{11}-X^{12}-X^{13}-X^{14}-X^{15}-X^{16})-X^{17}-Z^2$  or  $Z^1-X^1-X^2-X^3-X^4-X^5-X^6\text{-cyclo}(X^7-X^8-X^9-X^{10}-X^{11}-X^{12}-X^{13}-X^{14}-X^{15})-X^{16}-X^{17}-Z^2$ , where  $Z^1$ ,  $X^1$ ,  $X^2$ ,  $X^3$ ,  $X^4$ ,  $X^5$ ,  $X^6$ ,  $X^7$ ,  $X^8$ ,  $X^9$ ,  $X^{10}$ ,  $X^{11}$ ,  $X^{12}$ ,  $X^{13}$ ,  $X^{14}$ ,  $X^{15}$ ,  $X^{16}$ ,  $X^{17}$  and  $Z^2$  are each defined in the claim; and a method of screening for a compound able to bind a MCH type 1 receptor (MCH-1R) by measuring the ability of the compound to affect binding of the peptide to the receptor. This is obvious variation in view of claims 22-30, 34-37 and 42-43 in the co-pending application which disclose an optionally substituted peptide consisting of the structure of  $Z^1-X^1-X^2-X^3-X^4-X^5-X^6\text{-cyclo}(X^7-X^8-X^9-X^{10}-X^{11}-X^{12}-X^{13}-X^{14}-X^{15}-X^{16})-X^{17}-Z^2$ , where  $X^1$ ,  $X^2$ ,  $X^3$ ,  $X^4$ ,  $X^5$  is not present, and  $Z^1$ ,  $X^6$ ,  $X^7$ ,  $X^8$ ,  $X^9$ ,  $X^{10}$ ,  $X^{11}$ ,  $X^{12}$ ,  $X^{13}$ ,  $X^{14}$ ,  $X^{15}$ ,  $X^{16}$ ,  $X^{17}$  and  $Z^2$  are each defined in the claim; and a method of screening for a compound able to bind a melanin concentrating

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hormone (MCH) receptor by measuring the ability of the compound to inhibit binding of the peptide to the receptor. Both the claims of the instant application and the claims of the co-pending application are directed to an optionally substituted peptide having the structure of  $Z^1-X^1-X^2-X^3-X^4-X^5-X^6\text{-cyclo}(X^7-X^8-X^9-X^{10}-X^{11}-X^{12}-X^{13}-X^{14}-X^{15}-X^{16})-X^{17}-Z^2$ ; and a method of screening for a compound able to bind a MCH receptor by measuring the ability of the compound to inhibit binding of the peptide to the receptor. Thus, claims 1-3, 5-11, 14, 15 and 17-20 in present application and claims 22-30, 34-37 and 42-43 in the co-pending application are obvious variations of an optionally substituted peptide having the structure of  $Z^1-X^1-X^2-X^3-X^4-X^5-X^6\text{-cyclo}(X^7-X^8-X^9-X^{10}-X^{11}-X^{12}-X^{13}-X^{14}-X^{15}-X^{16})-X^{17}-Z^2$ ; and a method of screening for a compound able to bind a MCH receptor by measuring the ability of the compound to inhibit binding of the peptide to the receptor.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

10. No claims are allowed.

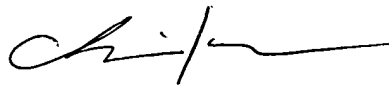
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Primary Patent Examiner



primary

**CHIH-MIN KAM**  
**PATENT EXAMINER**

CMK

August 31, 2006